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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/890,284	08/13/2001	Kazutaka Inoue		5139

7590 04/07/2004  
Law Office of Townsend & Banta  
601 Pennsylvania Avenue NW  
Suite 900 South Building  
Washington, DC 20004

EXAMINER

LAM, ANN Y

ART UNIT PAPER NUMBER

1641

DATE MAILED: 04/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/890,284

**Applicant(s)**

INOUE ET AL.

**Examiner**

Ann Y. Lam

**Art Unit**

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 09 January 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1 and 7 are rejected under 35 U.S.C. 102(e) as being anticipated by Flower, 5,830,175.

As to claim 1, Flower discloses a first circuit comprising a detection circuit for detecting a residual voltage developed in the transdermal or the transmucosal tissues based on current outputted from the negative output terminal, see column 5, lines 6-38; and second circuit (12) for determining a conduction state of current into the transdermal or the transmucosal based on the output detected by the first circuit, see column 7, lines 55-67.

As to claim 7, Flower discloses an apparatus comprising a preparation for iontophoresis, see column 3, line 24, holding a drug, see column 4, line 11; and a device having means for generating an electrical output through positive and negative output terminals to supply a drug for the preparation into transdermal or transmucosal tissue, see column 4, lines 56-63, and means for detecting a residual voltage developed

in the transdermal or the transmucosal to determine a conduction state of a current flowing into the transdermal or the transmucosal tissue based on voltage existing between the output terminals during an off-period of an output to determine a conduction state of a current flowing into the transdermal or the transmucosal tissue, see column 5, lines 6-23, and column 6, lines 23-26. (Applicant is claiming a device in this claim, and the Flower device is capable of determining the voltage existing between the output terminals during an off-period.)

Claims 1-7 are rejected under 35 U.S.C. 102(e) as being anticipated by McNichols et al., 5,047,007.

As to claims 1, 4 and 7, McNichols et al. disclose a first circuit comprising a detection circuit for detecting a reactive current flowing through a capacity component of impedance of the transdermal or the transmucosal tissues based on current outputted from the negative output terminal (column 10, lines 25-31) and/or a detection circuit for detecting a residual voltage developed in the transdermal or the transmucosal tissue based on a voltage existing between the output terminals during an off-period of an output, (see column 10, lines 25-31; and lines 51-56; which discloses alternatively coupling the voltage output between the first circuit branch and the second circuit branch, i.e., disclosing an off-period during which the detection circuit detects a reactive current or residual voltage in the transdermal or transmucosal tissue); and a second circuit (i.e., sensor-feedback means) for determining a conduction state of current into

the transdermal or the transmucosal based on the output detected by the first means, see column 9, lines 30-50, and column 10, lines 25-31.

As to claims 2 and 5, the detection circuit for detecting the reactive current includes a resistor coupled to the negative output terminal, a switch for sending one of positive and negative waveforms of current appearing across a resistor coupled to the negative output terminal (column 14, lines 28-43), and a capacitor for smoothing out the current waveform from the switch, see column 14, lines 11-51.

As to claims 3 and 6, the residual voltage includes a discharging resistor coupled between output terminals, see column 14, lines 28-43.

### ***Response to Arguments***

With respect to Applicant's arguments regarding the rejections of claims 3, 4 and 6 under Flower, the arguments are moot since those rejections are withdrawn.

With respect to Applicant's arguments regarding the rejections of claims 1 and 7 under Flower, Applicant is claiming a device in this claim, and the Flower device is capable of determining the voltage existing between the output terminals during an off-period.

With respect to Applicant's arguments regarding the rejections under McNichols, McNichols discloses alternatively coupling the voltage output between the first circuit branch and the second circuit branch (column 10, lines 25-31; and lines 51-56), thus disclosing an off-period during which the detection circuit detects a reactive current or residual voltage in the transdermal or transmucosal tissue.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is 571-272-0822. The examiner can normally be reached on M-Sat 11-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1641

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A.L.



LONG V. LE  
SUPERVISORY PATENT EXAMINER  
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64/05/07